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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,115	01/23/2001	Arthur W. Johnston	38830/253270	9625
23370	7590	03/19/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			BARRY, CHESTER T	
			ART UNIT	PAPER NUMBER
			1724	
DATE MAILED: 03/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/768,115

Applicant(s)

JOHNSTON ET AL.

Examiner

Chester T. Barry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Claim Construction

Applicants' specification (at page 3, last line) indicates that they understand hydroxyapatite to be a form of apatite:

Apatite in the form of hydroxylapatite (HA)

Applicants' specification (at page 9) indicates they understand that a "block" is any geometrical shape other than a sheet or membrane:

As used herein, the term "block" does not denote any particular geometrical shape, but rather that the material is not a sheet or membrane. Nonlimiting examples of "blocks" as this term is intended to be used include tubes, annular rings, as well as more conventional geometrical solids.

Accordingly, the expression, "in a rigid, porous form selected from a block and a sheet" is construed as "in any rigid, porous geometrical form other than a membrane."

Applicants state that the

efficiency of the purification material and the method for using it to reduce microbiological contaminants, as well as the flow rate of the fluid through the material, are a function of the pore size within the block and the influent fluid pressure.

(at page 25) and that average

pore size in a particular embodiment is kept to below several microns and more particularly to below about one micron, to preclude passage of cysts.

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(at page 26).

Anticipation and Obviousness Rejections

Claim 63 is rejected under 35 U.S.C. Sec. 102(e) as anticipated by Umezu. US published application 2002/0006427 to Umezu describes (at paragraph [0029]) adding, stirring, and mixing a binder slurry, e.g., an aqueous solution of polyvinyl alcohol (PVA) or polyethylene glycol (PEG), with hydroxyapatite powder, forming the apatite / binder slurry into a spherical form (parag [0032] – [0033]), and then sinter<sup>ing</sup>ed to form uniformly-porous (parag [0036], [0038]) ceramic spheres in the size range 0.01 to 10 mm. A summary is disclosed at parag [0042]:

[0042] The specific production process of composite spherical-shape ceramics according to the second aspect of the present invention comprises mixing a binder into a high purity calcium phosphate powder obtained by a known synthetic method, preferably wet synthesis and dry synthesis, preferably a hydroxyapatite, tricalcium phosphate, or tetracalcium phosphate, then shape the mixture by any method and sinter it at a temperature of 800 to 1500° C. to obtain a calcium phosphate ceramics superior in biocompatibility. As the method of shaping, a monoaxial press, rubber press, etc. may be used for easy shaping. Further, by mixing a burn-off substance in the binder, it is possible to make the ceramics porous after sintering. Porous ceramics facilitate the entry of osteoblasts and other tissue in the organism and a bone regenerating capability to be exhibited more suitably, when implanted in a bone loss portion. However, since the dynamic strength is poor, it is necessary to pay close attention at the time of use.

The size of pores on the surface of the spheres was 1 – 4 microns (parag [0055]). This pore size range is comparable to the average pore size of "below several microns" disclosed by applicants as suitable for immobilizing microorganisms, such as cysts.

Umezu's product is constructed and arranged so as not to preclude immobilization of microorganisms on a surface of the medium while also being constructed and arranged to not preclude an external agent, e.g., air or water, from contacting the immobilized microorganisms. In other words, Umezu's product is constructed and arranged so as to be capable of immobilizing microorganisms and being in contact with an agent external to the product itself, e.g., air or water, for example.

Accordingly, Umezu describes the claim 63 product. The claimed product reads on a single sphere having pores capable of immobilizing and contacting microorganisms. As claimed in claim 63, the product is merely intended for use in immobilizing microorganisms. Claim 64 and the doctrine of claim differentiation make clear that the product of claim 63 is not limited by the presence of microorganisms on the product.

Claim 64 is rejected under 35 U.S.C. Sec. 102(e) as anticipated by Example 57 of 6458162. See also Fig. 3 – Fig. 4.

Claim 63 is rejected under 35 U.S.C. Sec. 102(b) as anticipated by USP 4629464.

Claim 64 is rejected under 35 USC Sec 103(a) as obvious over Umezu in view of USP 6458162 to Koblish. Koblish Fig 3 and associated text suggests use of the Umezu

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material – in disk form – as a bioseparation filter medium in a flow through system.

Such use would effect retention of microorganisms on the filter block.

USP 5298205 is cited of interest. It is unclear whether any of the various materials applicants describe as being forms of "apatite" (see page 16-21 of applicants' specification) reads on any of the ceramic materials described or suggested by USP 5298205.

Objection(s)

Objection is made to Claims 63 – 64 for improper recitation of a Markush group: In claim 63, "form selected from a block and a sheet" must be changed to "form selected from the group consisting of a block and a sheet," or other acceptable claim drafting forms.

Action is Final

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The examiner notes that prior to Applicants' latest amendment, the claims were those shown at left below. New claims 63 – 64 substantially correspond to the claims shown at right below. The underlined portions indicate the limitations found in

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the claims at right that were not present in claims 61 – 62.

61. An immobilization and contacting medium for microorganisms, comprising apatite and a binder therefor, and is in the form of a rigid, porous block or a sheet.	An immobilization and contacting medium for microorganisms, comprising apatite and a binder therefor, wherein the medium is in a rigid, porous form selected from a block or a sheet, <u>further wherein the medium is constructed and arranged to immobilize microorganisms on a surface of the pores of the medium while also being constructed and arranged to permit an external agent to contact the immobilized microorganisms</u>
62. The immobilization and contacting medium of claim 61, further comprising one or more microorganisms disposed within the pores thereof.	An immobilization and contacting medium for microorganisms, comprising apatite and a binder therefor, wherein the medium is in a rigid, porous form selected from a block or a sheet, <u>further wherein the medium is constructed and arranged to immobilize microorganisms on a surface of the pores of the medium while also being constructed and arranged to permit an external agent to contact the immobilized microorganisms</u> further comprising one or more microorganisms disposed within the pores thereof.

The examiner notes that applicants cancelled claims 61 and 62 in response to various rejections based on prior art and other bases substantially related to patentability, e.g., Sec. 112(2<sup>nd</sup>).

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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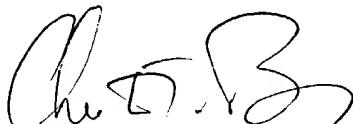
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Request

The examiner requests, but does not require, of course, that applicants amend claims rather than replace rejected claims with new claims. Speedier comprehension of the nature of the changes in claimed scope, and more efficient administration of Title 35, may result.

Drawings

The drawings submitted in this case after filing correspond to those of the parent.

A handwritten signature in black ink, appearing to read "Chestert T. Barry", is written over a horizontal line.

**CHESTERT T. BARRY  
PRIMARY EXAMINER**

571-272-1152